

## REMARKS

Claims 1, 2, 4, 8-16, 44, 46, 48-54, 57-64, and 66-73 are pending and under examination. Claims 1 and 16 have been amended. Claims 15 and 54 have been canceled. Support for the amendments can be found throughout the specification and the claims as filed. In particular, support for the amendment to claims 1 and 16 be found, for example, in original claims 11 and 13 and on page 56, lines 1-7. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Applicants appreciate Examiner Zhou's time and helpful discussion with Applicants' representative in the telephonic interview on June 27, 2007. During the interview, issues relating to the outstanding rejections were discussed. It is believed that the present response addresses the issues discussed during the interview.

Regarding the Previous Amendments

The Office Action indicates that the amendment filed October 31, 2006, has been acknowledged and that the amendment to the claims has been entered but not the amendment to the specification. Applicants point out that the amendment filed April 2, 2007, showed markings for the amendment to the title as filed in the response of October 31, 2006. Nevertheless, to make the record clear and in order to comply with the request in the present Office Action, the title has been amended as in the response filed October 31, 2006, with the present amendment showing markings relative to the original title.

Regarding the Priority Claim

In the previous response filed October 31, 2006, Applicants clarified the record with regard to the priority claim. In particular, contrary to the assertion in the previous and present Office Action, the present application has never claimed priority to German application number 10057589.7, filed November 21, 2000, or to any priority application.

In the telephonic interview with Examiner Zhou, he indicated that the most recent filing receipt reflects a priority claim to German application number 10057589.7 and requested that a formal correction of the filing receipt be filed. As discussed with Examiner Zhou and as

Applicants pointed out in the response as filed October 31, 2006, the only filing receipt received was mailed March 6, 2002, a copy of which was submitted with the previous response as Exhibit 1 and is submitted herewith again as Exhibit 1, and this filing receipt clearly shows that no priority claim has been made. As additional evidence that no priority claim has been made, also submitted herewith is a copy of the first page of the specification (Exhibit 2), which also clearly indicates that no priority claim has been made. 37 C.F.R. § 1.78 states as follows:

§ 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America...

(a)(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications...

(2)(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence(s) following the title.

Thus, Applicants respectfully submit that, in light of the fact that the first paragraph of the specification has no priority claim, the record is clear that there is no priority claim to any earlier filed application, let alone German application number 10057589.7.

Nevertheless, as requested by Examiner Zhou, the Office of Initial Patent Examination (OIPE) was contacted, and OIPE noted an error on the current filing receipt reflecting the priority claim to the German application. OIPE corrected the filing receipt and faxed same to Applicants' representative. Attached as Exhibit 3 is the corrected filing receipt dated July 20, 2007, which clearly shows that there is no priority claim. Applicants respectfully maintain that the present application makes no priority claim to an earlier filed application and that the record and the filing receipt reflects the correct priority claim.

Regarding the Objections to the Specification

The Office Action indicates that the specification is objected to for reciting trademarked terms such as “Windows” without capitalization. Applicants respectfully point out that the specification was previously amended in the response filed October 31, 2006, to include “®” to indicate trademarks. Nevertheless, as discussed with the Examiner in the telephonic interview, the specification has been amended on page 132 to indicate that the terms “Windows” and “Macintosh” are trademarks by all capitalization, as requested. Accordingly, Applicants respectfully request that the objection to the specification regarding trademarks be withdrawn.

Regarding the title and as discussed above, the title was previously amended in the response mailed April 2, 2007, showing markings for the amendment. Nevertheless, to make the record clear and since the April 2, 2007, response does not appear to have been entered, the title has been amended herewith with markings showing the amendment relative to the original title. Accordingly, Applicants respectfully request that the objection to the specification regarding the title be withdrawn.

Rejection Under 35 U.S.C. § 101

The rejection of claims 1, 2, 4, 8-16, 44, 46, 48-54, 57-64 and 66-73 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter is respectfully traversed. Applicants respectfully maintain, for the reasons of record, that the claimed methods are directed to statutory subject matter. Nevertheless, to further prosecution, claims 1 and 16 have been amended, as discussed with Examiner Zhou, to recite the step of providing an output to a user. Applicants respectfully maintain that the claimed methods are directed to statutory subject matter and, accordingly, respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 1, 2, 4, 8-16, 44, 46, 48-54, 57-64 and 66-73 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description is respectfully traversed. Applicants respectfully submit that the specification provides sufficient description and guidance for the claimed methods.

Applicants respectfully submit that the specification provides sufficient description and guidance for the claimed methods of classifying a population by drug responsiveness. Contrary to the assertion in the Office Action, Applicants respectfully submit that the specification teaches a variety of sample molecules that can be used in methods of the invention, including nucleic acids, polypeptides, and small molecules. The specification also teaches that an individual who has a disease or is in early stages of developing a disease has characteristic changes in expression of molecules in a cell, including changes in the expression of small molecules (page 7, lines 12-18). As acknowledged in the Office Action, the specification teaches numerous exemplary small molecules, for example, on page 16, line 28, to page 17, line 26. The specification additionally teaches that methods for analysis of small molecules are well known to those skilled in the art (page 116, line 19, to page 117, line 3), including textbooks such as Tietz Textbook of Clinical Chemistry 2nd ed., Burtis and Ashwood, eds., W.B. Saunders Co., Philadelphia (1994), and Tietz Textbook of Clinical Chemistry 3rd. ed., Burtis and Ashwood, eds., W.B. Saunders Co., Philadelphia (1999)(chapters of which were provided on the Information Disclosure Statement filed November 13, 2001). Accordingly, contrary to the assertion in the Office Action, Applicants respectfully submit that the specification provides sufficient description and guidance for determining the expression levels of small molecules. Nevertheless, to further prosecution, claims 1 and 16 have been amended to recite nucleic acid and polypeptide molecules.

Applicants respectfully submit that the specification provides sufficient description and guidance for the claimed methods. Accordingly, Applicants respectfully request that this rejection be withdrawn.

#### Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1, 2 4, 8-16, 44, 46, 48-54, 57-64 and 66-73 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. Applicants respectfully submit that the claims are clear and definite.

As discussed with Examiner Zhou in the telephonic interview, the clarity issue appears to relate to antecedent basis for the singular versus plural form of “multidimensional coordinate point.” Claims 1 and 16 have been amended as discussed with Examiner Zhou and to clarify

antecedent basis for the term “multidimensional coordinate point.” Applicants respectfully submit that the claims are clear and definite and request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

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**Date: August 6, 2007**

**Please recognize our Customer No. 41552  
as our correspondence address.**

## EXHIBIT 1

DAG / DLC  
07.0.

## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
✓ 09/919,360	✓ 07/30/2001	1743	726	✓ P-IS 4627	✓ 7	✓ 43	✓ 5

CONFIRMATION NO. 2535

## UPDATED FILING RECEIPT



\*0C000000007586415\*

✓ 23601  
CAMPBELL & FLORES LLP  
4370 LA JOLLA VILLAGE DRIVE  
7TH FLOOR  
SAN DIEGO, CA 92122

Date Mailed: 03/06/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

## ✓ Applicant(s)

Leroy E. Hood, Seattle, WA;  
Andrew F. Siegel, Shoreline, WA;

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted 09/25/2001

Projected Publication Date: 01/30/2003

Non-Publication Request: No

Early Publication Request: No

✓ \*\* SMALL ENTITY \*\*

## ✓ Title

Multiparameter analysis for drug response and related methods

Preliminary Class

436



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**LICENSE FOR FOREIGN FILING UNDER**  
**Title 35, United States Code, Section 184**  
**Title 37, Code of Federal Regulations, 5.11 & 5.15**

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**NOT GRANTED**

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## EXHIBIT 2

MULTIPARAMETER ANALYSIS FOR DRUG RESPONSE AND RELATED  
METHODS

BACKGROUND OF THE INVENTION

The present invention relates generally to methods  
5 of predictive medicine and more specifically to methods of  
determining expression profiles of an individual in response  
to a drug.

Every living organism utilizes genetic information  
in the form of discrete nucleotide sequences, called genes,  
10 to convey information for the proper development and  
function of the organism. Even simple organisms, such as  
bacteria, contain thousands of genes, and the number is many  
fold greater in complex organisms such as humans.  
Understanding the complexities of the development and  
15 functioning of living organisms requires knowledge of these  
genes.

For many years, scientists have searched for and  
identified a number of genes important in the development  
and function of living organisms. What was once a difficult  
20 and time consuming process has greatly accelerated in recent  
years due to advances in technology and directed projects  
aimed at identifying essentially all genetic information of  
an organism. The first draft of the human genome is now  
available, and more than 30 organisms have now had their  
25 entire genomes sequenced. The determination of the genome  
of additional organisms is currently being pursued.

### EXHIBIT 3



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address CORRESPONDENCE FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22303-1450  
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APPL. NO.	FILING OR 371(a) DATE	ART. UNIT	FILED REC'D	ATTY. DOCKET NO.	TOT. CLMS	IND. CLMS
09/919,360	07/30/2001	1631	1448	P-1S 4627	43	5

41552  
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 SAN DIEGO, CA 92122

CONFIRMATION NO. 2535

## CORRECTED FILING RECEIPT



\*0C000000024948107\*

Date Mailed: 07/20/2007

Receipt is acknowledged of this nonprovisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Leroy E. Hood, Seattle, WA;  
 Andrew F. Siegel, Shoreline, WA;

Power of Attorney: The patent practitioners associated with Customer Number **23601**.

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted: 09/23/2001

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US09/919,360**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

**\*\* SMALL ENTITY \*\***

**Title**

Multiparameter analysis for drug response and related methods

**Preliminary Class**

702

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An International (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pa/doc/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof

unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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#### **NOT GRANTED**

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